

**PHARMACY EXAMINING BOARD
MADISON, WI
MINUTES
AUGUST 13, 2003**

PRESENT: Cynthia Benning, R.Ph., Michael Bettiga, R.Ph., John Bohlman, R.Ph.; Georgina Forbes, Dan Luce, R.Ph.; Charlotte Rasmussen, Susan Sutter, R.Ph.

STAFF PRESENT: Tom Ryan, Bureau Director; William Black, Legal Counsel; Pamela Meicher, Program Assistant; DOE Staff

GUESTS: Shelley Raebel, Purdue Pharma; Paul Baum, Group Health Cooperative; Tom Engels, Pharmacy Society of Wisconsin; Jeanne Pawielski, PSW-Student; Nina Chen, DPH-3, Student; Sam Gadzichowski, DPA-3; Ryan Bendar, Pharmacy Student; Jennifer Goerge, Pharmacy Student DPH-4; and Rozalynn Flores, DPH-4 Pharmacy Student.

CALL TO ORDER

Susan Sutter, Chair, called the meeting to order at 9:00 a.m. A quorum of 7 members was present.

AGENDA

Amendments to agenda:

Pharmacy Inspection Report (L)
Distributor Self-Inspection Information Sheet (L)
Loss and Theft Report (M)
List of Pharmacists and Distributors Licensed
Pending Cases Report

MOTION: Michael Bettiga moved, seconded by John Bohlman, to approve the agenda as amended. Motion carried unanimously.

APPROVAL OF MINUTES OF JULY 9, 2003

Corrections to minutes:

Page 7 – Correct HIPAA number to a federally assigned number.

Page 8 – Correct the last sentence under Credentialing Transitions to read: Susan Sutter will work with Ms. Pond as the Board contact on the active practice pharmacy form.

Page 10- Correct the last sentence under the Sacred Heart Compliance question to read: Mr. Black will also caution the pharmacy that the prescriptions should be read and filled as a delegated act by a Medical doctor.

Page 13- Add Cynthia Benning will attend the Milwaukee discussion and Susan Sutter will attend the discussions at Madison and Wausau, on pain management.

Page 13- Correct the last sentence to read; The Board representative will ask other pharmacists at the next Wisconsin Pharmacy Forum meeting if they will suggest volunteers to assist in writing examination questions for the Board.

MOTION: Charlotte Rasmussen moved, seconded by Cynthia Benning, to approve the minutes of July 9, 2003 as amended. Motion carried unanimously.

ADMINISTRATIVE REPORT

Tom Ryan reported that the Board member workshop will be held on October 14, 2003, at the Madison Concourse Hotel. The Board noted that it has examinations scheduled that day. Mr. Ryan will advise Chair Susan Sutter how many candidates are scheduled for that date.

PRESENTATION OF PROPOSED STIPULATION IN THE MATTER CONCERNING AMERICAN HOMEPATIENT, INC.

DOE Attorney Michael Berndt presented a proposed stipulation in the matter concerning, American Homepatient, Inc. This matter will be deliberated on in closed session.

PRESENTATION OF PROPOSED STIPULATION IN THE MATTER CONCERNING PHARMACY BUYING GROUP OF AMERICA

DOE Attorney Michael Berndt presented a proposed stipulation in the matter concerning Pharmacy Buying Group of America. This matter will be deliberated on in closed session.

PRESENTATION OF PROPOSED STIPULATION IN THE MATTER CONCERNING SELECT SPECIALTY HOSPITAL

DOE Attorney Michael Berndt presented a proposed stipulation in the matter concerning Select Specialty Hospital. This matter will be deliberated on in closed session.

SUMMARY REPORTS ON PENDING COURT CASES, DISCIPLINARY CASES, ADMINISTRATIVE RULES AND LEGISLATION

The Board reviewed the active Administrative Rules on the Summary Reports and decided to withdraw the scope statement on records of dispensing errors. The Board also reviewed the status of rules that was provided in the agenda packet. William Black, Legal Counsel, will provide information on the federal central fill regulation at a future meeting. Mr. Black will also provide the Board with the scope statement relating to significant controlled substances and

revise the temporary location change scope statement. Mr. Black advised the Board that the Department will schedule the hearing on absence of pharmacists, as soon as practicable after it is returned from the legislature.

MOTION: Cynthia Benning moved, seconded by Michael Bettiga, to withdraw the scope statement on records of dispensing errors. Motion carried unanimously.

WIS. ADMIN. CODE § PHAR 2.03 (4) PARTIAL REPEAL

The scope statement to make admission requirements for all required professional examinations consistent with national standards and to simplify and streamline the application process was presented to the Board. After a brief discussion, the Board agreed to approve the scope statement, partially repealing Wis. Admin. Code § 2.03 (4) for publication.

MOTION: Cynthia Benning moved, seconded by John Bohlman, to approve the scope statement partially repealing Wis. Admin. Code § Phar 2.03 (4). Motion carried unanimously.

REVIEW OF RULE DRAFT – PHARMACY TEMPORARY LOCATION CHANGE

William Black provided the Board with preliminary language relating to a temporary change of location of a pharmacy in response to an emergency, natural or manmade disaster. The Board reviewed the language. Dan Luce will provide more information from other states. Considerations recommended for the proposed language include: security, integrity of drugs, communications, transfer of license and DEA notification.

WIS. ADMIN. CODE § 8.05 (7) – CHANGE OF DOSAGE FORM

The Board discussed and reviewed the Drug Enforcement Administration letter and Frequently Asked Questions with respect to what pharmacists may change on a prescription written for Schedule II-V controlled substances. The Board agreed that pharmacists have a corresponding responsibility with the prescriber that the prescription contains the required elements.

COMPLIANCE QUESTION –DAVID HJORTNAES, R.PH.- MILWAUKEE, WI

William Black will draft a letter to David Hjortnaes, R.PH., advising him that a computer generated label placed on a prescription containing the pharmacist's initials is sufficient; a retail pharmacy location can leave exterior lights on all night, even though it's closed; the Joint Commission is not law; there is no law restricting food in any hospital refrigerator where drugs are stored; and a pharmacist is required to have an unknown patient sign a C-II prescription if the party is unknown to the pharmacist (this is enforced).

COMPLIANCE QUESTION – SENATOR MICHAEL ELLIS – NEENAH, WI

William Black will draft a letter in response to Senator Ellis' letter, explaining that moving drugs between two facilities falls under the DHFS rules, and that the Board suggests he review the DHFS rules.

COMPLIANCE QUESTION – CALUMET PHARMACY – CHILTON, WI

William Black told the Board that he has advised Calumet Medical Center that their questions fall under the Wis. Admin. Code § HFS 124.15, and that they need to review their plans with the appropriate officials at the Department of Health and Family Services (DHFS). Mr. Black has sent the information relating to the Calumet Medical Center questions to Doug Englebert, at DHFS.

COMPLIANCE QUESTION – KEITH KOSCIELSKI, R.PH. – MERRILL, WI

William Black will draft a letter to Keith Koscielski, R.Ph., advising him that it is the responsibility of the doctor to monitor patients per medical practice, not the pharmacist; and that it is permissible to fax information instead of performing the transfer verbally between pharmacists.

VARIANCE REQUEST – DAVID WINROW, R.PH. – MARSHFIELD, WI

William Black will draft a letter to David Wunrow, R.Ph., requesting more information on the process of the call center.

COMPLIANCE QUESTION – LORRAINE M. MOBLEY, R.PH., C.PH. – GAINESVILLE, FL

William Black will draft a letter to Lorraine M. Mobley, R.Ph., C.Ph., advising her that under the situation she explained, the company is not a pharmacy, therefore, a license is not required. He will further advise Ms. Mobley that she cannot designate a pharmacy as such if it is not a pharmacy.

PHARMACY SELF-INSPECTION INFORMATIONAL SHEET

The Board noted the draft of the Pharmacy Self-Inspection Information Sheet, provided by Kris Hendrickson. The form has been updated, covering the most frequently occurring problems of self-inspections.

PHARMACY INSPECTION REPORT

Greg Raube and Celina Kobs, DOE, led the discussion on the Pharmacy Inspection Report. They sought input from Board, to help improve the inspection process and the amount and quality of information collected. The Board suggested that if a distributor or a manufacturer has had a FDA or DEA inspection, the distributor or manufacturer must provide that report to DOE.

Differences noted during the discussion were that the FDA report addresses the integrity of the drugs, whereas, a DEA report addresses security. The Board identified items that they would like to see on the Pharmacy Inspection Report. Those items include: consultation with a patient; technician ratio (4/1); alarm system; a biennial inventory; and the addition of a narrative section. The Board will review the Pharmacy Inspection Report and return to the next meeting with follow-up suggestions. Mr. Raube and Ms. Kobs will provide an updated draft of the inspection form for the next Board meeting

INFORMATIONAL ITEMS

Noted.

CLOSED SESSION

MOTION: Charlotte Rasmussen moved, seconded by Michael Bettiga to convene to closed session to deliberate on cases following hearing (Wis. Stat. § 19.85 (1) (a)); consider closing disciplinary investigation with administrative warning (Wis. Stat. § 19.85 (1) (b), and Wis. Stat. § 440.205); consider individual histories or disciplinary data (Wis. Stat § 19.85 (f)); and to confer with legal counsel (Wis. Stat § 19.85 (1) (g)). Motion carried by roll call vote: Cynthia Benning-yes, Michael Bettiga-yes, John Bohlman-yes, Georgina Forbes-yes, Dan Luce-yes, Charlotte Rasmussen-yes, Susan Sutter-yes.

Open session recessed at 11:35 a.m.

RECONVENE INTO OPEN SESSION IMMEDIATELY FOLLOWING CLOSED SESSION

MOTION: Charlotte Rasmussen moved, seconded by Michael Bettiga, to reconvene into open Session at 1:35 p.m. Motion carried unanimously.

VOTING ON ITEMS DELIBERATED OR CONSIDERED IN CLOSED SESSION

ACCEPT EXAM SCORES

MOTION: Michael Bettiga moved, seconded by Dan Luce, to accept all the examination scores as provided by the Examinations Office. Motion carried unanimously.

REQUEST FOR HEARING

STEPHEN C. DEGUTIS

MOTION: John Bohlman moved, seconded by Charlotte Rasmussen, to deny the request for a hearing in the matter of Stephen C. Degutis. His request for

a Class I hearing did not meet the requirements of Wis. Admin. Code section RL 1.07 (3). Motion carried unanimously.

STIPULATIONS

AMERICAN HOMEPATIENT, INC.

MOTION: Charlotte Rasmussen moved, seconded by Michael Bettiga, to adopt the Final Decision, Order and Stipulation in the matter of American Homepatient, Inc. John Bohlman abstained. Motion carried.

PHARMACY BUYING GROUP OF AMERICAN

MOTION: Dan Luce moved, seconded by Georgina Forbes, to adopt the Final Decision, Order and Stipulation in the matter of Pharmacy Buying Group of America. Michael Bettiga abstained. Motion carried.

SELECT SPECIALTY HOSPITAL

MOTION: Dan Luce moved, seconded by Charlotte Rasmussen, to adopt the Final Decision, Order and Stipulation in the matter of Select Specialty Hospital. Michael Bettiga abstained. Motion carried.

REQUEST FOR THREE MONTH STAY WITH MODIFICATIONS

ROGER IVERSON

MOTION: Cynthia Benning moved, seconded by Michael Bettiga, to grant a three month stay of suspension in the matter of Roger Iverson, modify his order to allow two hours of pharmacy in-charge a week, disallow opening or closing of the pharmacy, and deny his request for unobserved urine samples. Motion carried unanimously.

REQUEST FOR FULL LICENSURE

DAVID KLEINGARTNER, R.PH.

MOTION: Michael Bettiga moved, seconded by Georgina Forbes, to grant full licensure to David Kleingartner, R.Ph. Motion carried unanimously.

REQUEST FOR STAY – JANET KRUEGER

MOTION: Dan Luce moved, seconded by Charlotte Rasmussen, to grant a three month stay of suspension in the matter of Janet Krueger. Motion carried unanimously.

REQUEST FOR FULL LICENSURE

JOHN LITZENBERG, R.PH.

MOTION: Charlotte Rasmussen moved, seconded by Michael Bettiga, to grant full licensure to John Litzenberg, R.Ph. Motion carried unanimously.

REQUEST FOR STAYS

DONALD LEETZ

MOTION: Michael Bettiga moved, seconded by Georgina Forbes, to grant a three month stay of suspension in the matter of Donald Leetz and to deny his Order modification until there is support from his therapist. Motion carried unanimously.

LANCE LUNDSTAD

MOTION: Dan Luce moved, seconded by Charlotte Rasmussen, to grant a three month stay of suspension in the matter of Lance Lundstad. Motion carried unanimously.

LUIGI MICELI

MOTION: Michael Bettiga moved, seconded by Georgina Forbes, to grant a three month stay of suspension in the matter of Luigi Miceli. Motion carried unanimously.

THOMAS G. PIRE, RPH

MOTION: Dan Luce moved, seconded by Georgina Forbes, to grant a three month stay of suspension in the matter of Thomas G. Pire, R.Ph., and to change his Order, reducing his therapy to twice a month, until he returns to work. Motion carried unanimously.

JOHN SCHMITT

MOTION: Dan Luce moved, seconded by Georgina Forbes, to grant a three month stay of suspension in the matter of John Schmitt, deny any modification, and remind him that his reports to the department need to be on time and the reports must be made by a supervising pharmacist, not by his employer. Michael Bettiga abstained. Motion carried.

GREGORY TECHE

MOTION: Charlotte Rasmussen moved, seconded by Georgina Forbes, to grant a three month stay of suspension in the matter of Gregory Teche. Motion carried unanimously.

CASE CLOSING

MOTION: Dan Luce moved, seconded by John Bohlman, to close case 02 PHM 022, for insufficient evidence. Motion carried unanimously.

ADJOURNMENT

MOTION: Dan Luce moved, seconded by Georgina Forbes, to adjourn the meeting at 2:07 p.m. Motion carried unanimously.

Next Meeting Tuesday, September 9, 2003